

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Vladimir A. Stoy **EXAMINER:** Alvin J. Stewart
 Gerald Gontarz

SERIAL NO.: 10/625,390 **ART UNIT:** 3738

FILED: July 23, 2003

FOR: Spinal Nucleus Implant

Commissioner for Patents
P.O. Box 1450
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DECLARATION OF GERALD GONTARZ UNDER 37 CFR § 1.131

Sir:

I, Gerald Gontarz, do aver that I, along with Vladimir Stoy, conceived the claimed subject matter in the above-identified patent application in the U.S. prior to the filing date of United States Patent Application Publication Number 2002/0183848 to Ray et al. ("Ray").

The Ray application was filed on July 24, 2002 and was published on December 5, 2002. The Ray application is a continuation of application No. 09/286,047, filed on April 5, 1999, according to the bibliographic information on the face of the published Ray application. However, I, along with Dr. Stoy, conceived the claimed subject matter before April 5, 1999. In support thereof, I am attaching true copies of two sheets from my laboratory notebook with notebook entries. These sheets from my laboratory notebook clearly show and support the claimed subject matter in the instant application.

The sheets labeled "A" and "B" of my laboratory notebook clearly show conception and reduction to practice of a spinal nucleus implant that has shape memory from an Aquacryl polymer, i.e., a swellable, biomimetic plastic, having a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, the biomimetic plastic having an inherent shape in which it has a relaxed polymer

network in a state of full hydration, having an insertion shape in which it is at least partially dehydrated to a xerogel state and formable into a compacted mode for maximum efficiency of surgical insertion, and capable of anisotropic expansion due to partial rehydration in situ into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state, the anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes. The notes and tables which I prepared and memorialized in my laboratory notebook clearly support the claimed subject matter of the instant application.

References to Li Medical in the attached notebook pages relate to a company that was considered for manufacture of instruments for insertion of the spinal nucleus implant. The disclosure of the implant to Li Medical personnel was made under confidentiality pursuant to a collaboration agreement and was not made for purposes of selling spinal nucleus implants.

Further still, these sheets from my laboratory notebook were prepared before April 5, 1999 and clearly demonstrate a conception and reduction to practice before the filing date of Ray. See, for example, the "spinal nucleus swelling in salt solution" measurements on the page labeled "A", the reference to "aquacryl" and "spinal nucleus that has a shape memory" on the page labeled "B", and the specific indication on the page labeled "B" that the samples were saved. As can be seen from the specification of the present application, e.g., Example 1, Aquacryl was used as a hydrogel in accordance with the invention. Therefore, Ray is not prior art to the instant application and cannot be applied against the claimed subject matter.

I am aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. All statements herein made of my own knowledge are true and all statements herein made on information and belief are believed to be true.

Respectfully,

MARCH 6, 2009

Date

Gerald Gontarz
Gerald Gontarz

A

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Spinal Nucleus Swelling in polio patients

SAMPLE	Time
26.9.77-A	4.20.10
B	3.54.26
26.2.74-a	4.43.03
S	4.44.13
C	4.33.46
I	3.76.11
E	3.21.09
F	2.89.86

B

10/2/74

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Medical Spinal Nucleus

will now make "mold available" type aquacryl in
 to make a spinal nucleus that has a shape memory.
 98% w.c. aquacryl as a base will come long, straight,
 straight, then arch in saline. These will be equilibrated
 in 10% NaCl, then concentrated as follows:

CURRENT COMPOSITION:		NaCl		NaSCN		Water	
initial water content:		0.8%		0.8%		0.8%	
at NaCl concentration:		0.8%		0.8%		0.8%	
	Weight	Polymer w	w2	NaSCN	Weight	Water	Weight
Initial state:	342.80	37.89	0.1100				
Swollen state:	283.81	37.89	0.1439	22.8124	241.0547		
		Liquid vol.	Target wt:	Pol conc:			
Target concentration:	45.6%	60.24878	87.94	43.9%			
	80.6%	45.2249	82.91	45.5%			
Target:	53.6%	41.11349	78.80	47.6%			
	60.0%	37.89733	78.37	50.0%			
With evaporation		175.87 g of water					
by adding		60.24878 g of NaSCN					

will shape these into spirals and heat to 100°C for
 15 minutes in order to insill a shape. This will be
 washed and plasticized as normal procedures.
 Sample saved as 16-Q-107-A